REMARKS

Claims 1-11, 13 and 15-31 are pending in this application. By this Amendment, claim 6 is amended. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Applicants sincerely acknowledge the Office Action's indication that claims 1-10, 16-18, 22-28 and 31 define patentable subject matter. However, for at least the reasons set forth below, Applicants respectfully submit all pending claims are in condition for allowance.

A. The Office Action objects to the drawings. Applicants respectfully submit that the enclosed Appendix A provides exemplary support for the objected to recited features in claims 1, 16, 22 and 29 from the drawings. However, the claimed invention is not intended to be so limited. Withdrawal of the objection to the drawings is respectfully requested.

B. The Office Action rejects claims 1-11, 13 and 15-31 under 35 U.S.C. §112, first paragraph. The rejection is respectfully traversed.

The Office Action asserts that the specification does not enable one of ordinary skill in the art how to achieve a signal capable of inducing pseudo-spontaneous activity in the auditory nerve. Applicants respectfully disagree.

1) The specification provides and describes test procedures and simulated results that produce desynchronized auditory nerve response that are then described as pseudo-spontaneous activity. The simulated results from the test procedures produce pseudo-spontaneous activity

at least exemplary amplitude, waveforms and frequency (e.g., inter-pulse periods). See Figures 15 and 9-10.

2) The specification provides and describes characteristics of signals that will result in pseudo-spontaneous activity in the auditory nerve. Such characteristics include at least exemplary frequency (e.g., inter-pulse periods), waveforms and amplitude and exemplary methods of application to the auditory nerve and exemplary apparatus for application to the auditory nerve. See Figures 11-13.

3) The specification provides and describes objective criteria for determining whether a signal is a pseudo-spontaneous driving signal based on actual effects generated in an auditory nerve, (e.g., whether the affected auditory nerve exhibits stochastically independent neural activity).

4) See at least U.S. Patent Nos. 6,078,838 and 6,295,472.

Thus, Applicants respectfully submit that the specification enables one of ordinary skill in the art to be capable of inducing pseudo-spontaneous activity in the auditory nerve using described methods or apparatus. Withdrawal of the rejection of 1-11, 13 and 15-31 under 35 U.S.C. §112, first paragraph is respectfully requested.

C. The Office Action rejects claims 1-11, 13 and 15-31 under 35 U.S.C. §112, second paragraph. The rejection is respectfully traversed.

Applicants respectfully submit that '[I]n a normal cochlea the inner hair cell-spiral ganglion is inherently "noisy" (i.e., there is a high background of activity in the absence of sound)

resulting in spontaneous activity in the auditory nerve. ... [A]ccording to the preferred embodiments of the present invention, the artificial induction of a random pattern of activation in the auditory nerve of a tinnitus patient or a hard-of-hearing patient, mimics the spontaneous neural activation of the auditory nerve, which routinely occurs in an individual with normal hearing and lacking tinnitus. The artificially induced random pattern of activity is hereafter called "pseudospontaneous".' See page 14, lines 6-17 of the present specification. Withdrawal of the rejection of 1-11, 13 and 15-31 under 35 U.S.C. §112 is respectfully requested.

D. The Office Action rejects claims 11, 13, 15, 20-21 and 29-30 under 35 U.S.C. §103(a) over U.S. Patent No. 6,377,693 to Lippa et al. (hereafter "Lippa"). The rejection is respectfully traversed.

Claim 11

1) The Office Action asserts "[I]t is **fair to conclude** that for the invention of Lippa to be effective in the reduction of tinnitus and/or improving sensory response, the signal **must** reach the user's acoustic nerve" (emphasis added). See Page 5, lines 5-7 of the May 4, 2004 Office Action. Applicants respectfully disagree.

Applicants respectfully submit that Lippa discloses a hearing aid system of the "bone conduction transmission" type. Such a general type of hearing aid is disclosed in U.S. Patent No. 4,982,434 to Lenhardt et al. (hereafter "Lenhardt"). See column 1, lines 45-51 of Lippa, which incorporates the Lenhardt patent in its entirety. Applicants respectfully submit that in Lenhardt and Lippa, the "bone conduction transmission" type apparatus and method were

presented as an alternative to using the auditory nerve for "hearing". See column 1, lines 57-68, column 2, lines 28-47, column 3, lines 7-9 of Lenhardt.

Applicants respectfully submit that Lippa teaches a method and apparatus for treating tinnitus by (a) masking tinnitus through the use of ultrasonic frequency signals that are generated in an ultrasonic frequency range and applied physically to a second body part of the patient (Lippa column 1, lines 37-39), and (b) transposing human speech into the ultrasonic range applying said signals vibrationally to the body while masking stimuli in the auditory range are applied in a conventional manner. Thus, Lippa discloses an improvement to the Lenhardt process. See column 2, lines 37-41 of Lippa reproduced below (emphasis added).

> The ultrasonic stimuli (above 20 kHz) perceived by the brain have been **clinically shown to be effective** in masking the ringing or buzzing in the ears associated with tinnitus, while not interfering with the perception of speech or other normal sounds.

As stated in MPEP §2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Applicants respectfully submit that there is nothing in Lippa that would lead one of ordinary skill in the art to modify the disclosed "bone conduction transmission" an auditory scheme generating a second signal that causes pseudo-spontaneous activity or a second signal configured to induce a random pattern of activation in the auditory nerve and

combinations thereof as variously recited. Further, Applicants respectfully submit that Lippa specifically and as a whole teaches away from this modification.

In addition, Applicants respectfully request that the Office Action provide support for the assertion that it is "**fair to conclude** that for the invention of Lippa to be effective in the reduction of tinnitus and/or improving sensory response, the signal must reach the user's acoustic nerve". As described above, Applicants respectfully submit that the assertion is incorrect.

2) Applicants respectfully submit that Lippa does not teach or suggest at least features of generating a second signal that causes pseudo-spontaneous activity in an acoustic nerve, and applying the combined signal to the acoustic nerve and combinations thereof as recited in claim 11. Applicants respectfully submit Lippa teaches away from at least these recited features and combinations thereof.

3) The Office Action currently asserts Lippa discloses a combination of (12, 22) as providing a high frequency signal applied via electrode (column 2, 34-36) not a headphone or vibrational transducer. See Item 1, page 7 of the May 4, 2004 Office Action.

Applicants respectfully submit Lippa teaches a method and apparatus for treating tinnitus by (a) masking tinnitus through the use of ultrasonic frequency signals that are generated in an ultrasonic frequency range and applied physically to a second body part of the patient (Lippa column 1, lines 37-39), and (b) transposing human speech into the ultrasonic range applying said signals vibrationally to the body while masking stimuli in the auditory range are applied in a

conventional manner. See the Summary of the Invention in Lippa. Applicants respectfully submit that Lippa discloses the selected body portion being only applying a signal to the exterior of the head/skull either using a screw or applying a signal to the skin. See column 5, lines 23-30 of Lenhardt; column 2, lines 3-4, 26-33, 47-51, 59-60 and claims 1, 2, 6, 7 and 9 of Lippa.

a) Applicants respectfully submit that an electrical signal applied to an electrode attached to the skin of the head would have to be applied at power levels sufficient to cause pain, in order to have any chance of stimulating the auditory nerve. This is because an electrical signal applied to the exterior of the skull sees a sizable insulator which includes at least the skin, fluids, tissue and bone of the head surrounding the auditory nerve. Thus, it is extremely unlikely that any signal applied through electrodes on the skin could even stimulate the auditory nerve let alone stimulate it in such a way as to cause pseudo-spontaneous activity without causing significant injury and/or pain to the patient.

Moreover, if such an electrical signal could somehow stimulate the auditory nerve fiber without severely injuring the patient, then adjacent nerve fibers activated by that electrical signal would be statistically dependent, not independent. Thus, even if an electrical signal applied to electrodes attached to the skin of the head could possibly stimulate the auditory nerve, the electrical signal will not generate statistically independent activity of the auditory nerve fibers.

b) Applicants respectfully submit that an electrode that vibrationally or physically applies signals to the skin or the head as disclosed in Lippa would not result in pseudospontaneous result in pseudo-spontaneous activity in an acoustic nerve or teach or

suggest at least features of generating a second signal that causes pseudo-spontaneous activity in an acoustic nerve and combinations thereof.

Claims 22 and 30

Applicants respectfully submit that these claims depend from claims 11 and 29 and therefore further defines features of the recited independent claims. For example, "a frequency above approximately 2 kHz" can be interpreted as setting a lower limit of a frequency range.

For at least the reasons set forth above, Applicants respectfully submit that claim 11 defines patentable subject matter. Claim 29 defines patentable subject matter for at least reasons similar to claim 11. Claims 13, 15, 19-21 and 30-31 depend from claims 11 and 29 respectively and therefore also recite patentable subject matter for at least that reason as well as their additionally recited features. Withdrawal of the rejection of claims 11, 13, 15, 20-21 and 29-30 under 35 U.S.C. §103 is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. Favorable consideration and prompt allowance are earnestly solicited.

If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney, **Carl R. Wesolowski**, at the telephone number listed below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
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APPENDIX A

1. (Previously Presented) A cochlear implant system, comprising:

a signal generator (e.g., 1206) that generates a second signal (e.g., 1102, line between 1206 and 1210) capable of causing pseudospontaneous activity in an auditory nerve;

a signal processor (e.g., 1210) that combines a first signal (e.g., 1104, line between 1204 and 1210) that represents sound and the second signal to output a combined signal (e.g., Figure 11, 1216); and

a stimulation unit (e.g., 1220) coupled to the signal processor that receives (e.g., 1222 or 1226) the combined signal from the signal processor, wherein the stimulation unit is configured to apply (e.g., 1224) the combined signal (e.g., Figure 11, 1206) to the auditory nerve.

16. (Previously Presented) An auditory prosthesis for receiving an auditory signal representing sound and supplying an electrical signal which is adapted to stimulate the auditory nerve of a person, comprising:

pseudospontaneous generation means (e.g., 1206) for generating a pseudospontaneous driving signal (e.g., 1102, line between 1206 and 1210);

transducer means (e.g., 1204, 1210) adapted to receive the auditory signal (e.g., 1104) and the pseudospontaneous driving signal for transforming the auditory signal and the pseudospontaneous driving signal to an electrical input signals; and

stimulation means (e.g., 1220), operatively coupled (e.g., 1226) to the electrical input signals generated by the transducer means, for stimulating the auditory nerve at defined locations (e.g., 1224) within the cochlea, wherein at least one (e.g., 1102) of the plurality of electrical signals (e.g., 1102, 1104) is configured to cause statistically independent activity in a plurality of nerve fibers of an auditory nerve.

22. (Previously Presented) A neural prosthetic apparatus, comprising:

a signal generator (e.g., 1206) that generates a second signal (e.g., line between 1206 and 1320);

a signal processor (e.g., 1320) that combines a first signal (e.g., line between 1310 and 1320) that represents sound and the second signal to output a combined signal, wherein a carrier signal is modulated with the combined signal (e.g., line between 1320 and 1320) ; and

stimulation unit (e.g., 1330) coupled to the signal processor that receives and demodulates the carrier signal to obtain the combined signal from the signal processor for application to the auditory nerve, wherein the second signal includes at least fluctuations in amplitude greater than a prescribed amount at a frequency above approximately 2 kHz.

29. (Previously Presented) A method of modifying (e.g., Figure 10) a neural prosthetic apparatus that receives an information signal and supplies a corresponding electrical signal to stimulate an auditory nerve (e.g., Figure 15), comprising:

providing a pseudospontaneous signal generator (e.g., 1206) that generates a second signal (e.g., Figure 9); and

providing an electrical coupling means (e.g., 1222) for supporting an electrical connection from the pseudospontaneous signal generator to at least one electrical contact (e.g., 1224), and wherein the second signal is configured to induce a random pattern of activation in the auditory nerve mimicking the spontaneous neural activity of the auditory nerve.

29. (Previously Presented) A method of modifying a neural prosthetic apparatus (e.g., 1310 and 1330') that receives an information signal and supplies a corresponding electrical signal to stimulate an auditory nerve (e.g., Figure 15), comprising:

providing a pseudospontaneous signal generator (e.g., 1206) that generates a second signal (e.g., line between 1206 and 1330); and

providing an electrical coupling means (e.g., 1330) for supporting an electrical connection from the pseudospontaneous signal generator to at least one electrical contact, and wherein the second signal is configured to induce a random pattern of activation in the auditory nerve mimicking the spontaneous neural activity of the auditory nerve.